

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	: Dudley <i>et al.</i>	Customer No.	: 11030
Serial No.	: 10/829,618	Confirmation No.	: 7286
Filed	: 4/20/2004	Group Art Unit	: 1627
Examiner	: Jean-Louis, Samira		
For	: Androgen Pharmaceutical Composition and Method for Treating Depression		

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit the present Information Disclosure Statement in conjunction with a Preliminary Amendment and Request for Continued Examination and requisite fee of \$810.00 in the application noted above.

Enclosed herewith for consideration by the Patent and Trademark Office in regard to the pending claims of the above-identified application are the patents and/or publications relied upon and references cited in a Petition for Accelerated Examination during prosecution of the related pending U.S. applications or issued U.S. patents listed below. Also provided for the Examiner's convenience is a listing of the related and co-pending U.S. applications and substantive communications therein, as well as search reports issued and oppositions filed in related or co-pending foreign applications. In compliance with 37 C.F.R. §1.56, such documents are listed on the enclosed Form PTO-1449. Applicants note that additional Information Disclosure Statements will be submitted to identify all additional information including, among other things, materials cited in the related applications listed below.

To assist with the review of the Information Disclosure Statements, Applicants hereby formally request an in-person interview with the Examiner and Supervising Examiner for this application. The Examiner is requested to contact the Applicants' Attorney at (212) 408-2500

to schedule a mutually convenient date and time such that the Applicants can provide assistance or additional information as required.

This Information Disclosure Statement is submitted according to the following selected paragraph(s):

- ☒ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(b) (1) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d); (2) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application; (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.
- ☐ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(c) prior to either a final action or a notice of allowance. Payment for the fee required by 37 C.F.R. §1.17(p) is hereby authorized to be charged to Deposit Account No. 02-4377.
- ☐ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(c), with a statement under, 37 C.F.R. §1.97(e) prior to either a final action or a notice of allowance. The undersigned hereby states that (check one):
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the information disclosure statement.

☐ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(d), with a statement under 37 C.F.R. §1.97(e), after a final action or a notice of allowance but prior to payment of the issue fee. Payment for the fee required by 37 C.F.R. §1.17(p) is hereby authorized to be charged to Deposit Account No. 02-4377. The undersigned hereby petitions that this Information Disclosure Statement be considered prior to issuance of the patent. The undersigned hereby states that (check one):

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the information disclosure statement.

☐ The references listed on the accompanying PTO-1449 were either cited by the Examiner or previously submitted in parent application U.S. Serial No. _____, filed _____. Pursuant to 37 C.F.R. § 1.98(d), the references are not required if the earlier application is identified and relied upon for an effective filing date under 35 U.S.C. § 120 and therefore are not enclosed herewith.

Related Application Disclosure

☒ Applicants would like to bring to the attention of the Examiner the following related patent applications, which are also listed on the accompanying PTO-1449:

Application Serial No.	Filing Date
09/651777 (now US 6,503,894)	08-30-2000
09/703753 (abandoned)	11-01-2000
09/892981 (abandoned)	06-27-2001

10/033101 (abandoned)	10-19-2001
10/046454 (abandoned)	10-19-2001
10/098232 (abandoned)	03-15-2002
10/099725 (abandoned)	03-15-2002
10/153468 (abandoned)	05-21-2002
10/248267 (abandoned)	01-03-2003
10/273484 (abandoned)	10-18-2002
10/436380 (now US 7,611,727)	05-12-2003
10/456868	06-06-2003
10/787071 (abandoned)	02-25-2004
10/825540 (abandoned)	04-15-2004
10/828678 (abandoned)	04-20-2004
10/867435	06-14-2004
10/867445	06-14-2004
10/925421	08-24-2004
11/399642	04-06-2006
11/402682	04-11-2006
11/402986	04-11-2006
11/549083	10-12-2006
11/662339	09-24-2007
11/925421	10-26-2007
12/052337	03-20-2008
12/543541	08-19-2009
12/609473	10-30-2009

Disclosure of Office Actions and Responses in Related Applications

- ☒ Applicants would like to bring to the attention of the Examiner the following Office Actions issued in related patent applications and Responses to Office Actions filed in such applications, which are also listed on the accompanying PTO-1449:

11/402986	05-14-2010 Final Office Action
11/402986	02-22-2010 Response to Non-Final Office Action
11/402986	08-20-2009 Non-Final Office Action
11/402986	05-15-2009 Response to Non-Final Office Action
11/402986	11-17-2008 Non-Final Office Action
11/402682	03-17-2010 RCE and Response to Final Office Action
11/402682	09-17-2009 Final Office Action
11/402682	06-02-2009 Response to Non-Final Office Action
11/402682	12-02-2008 Non-Final Office Action
11/399642	10-15-2010 Final Office Action
11/399642	08-09-2010 Response to Non-Final Office Action
11/399642	02-08-2010 Non-Final Office Action
11/399642	11-16-2009 Response to Non-Final Office Action
11/399642	05-14-2009 Final Office Action
11/549083	09-27-2010 RCE and Response to Final Office Action
11/549083	03-25-2010 Final Office Action
11/549083	01-08-2010 Response to Notice of Non-Compliant Amendment
11/549083	10-13-2009 Response to Non-Final Office Action
11/549083	10-13-2009 Declaration of Norman Weiner
11/549083	06-22-2009 Non-Final Office Action
11/549083	04-01-2009 RCE and Response to Final Office Action

11/549083	01-14-2009 Final Office Action
11/549083	10-23-2008 Declaration of Norman Weiner
11/549083	10-23-2008 Response to Non-Final Office Action
11/549083	10-23-2008 Declaration of Drs. Ramana Malladi and Jodi Miller (37 CFR 1.131)
11/549083	10-23-2008 Petition to Correct Inventorship
11/549083	04-24-2008 Non-Final Office Action
11/549083	12-06-2007 Non-Final Office Action
12/052337	09-29-2010 RCE and Response to Final Office Action
12/052337	03-29-2010 Final Office Action
12/052337	11-16-2009 Response to Non-Final Office Action
12/052337	05-15-2009 Non-Final Office Action
09/892981	12-11-2006 Final Office Action
09/892981	09-28-2006 Response to Non-Final Office Action
09/892981	03-28-2006 Non-Final Office Action
09/892981	12-16-2005 RCE and Response to Final Office Action
09/892981	06-21-2005 Final Office Action
09/892981	04-08-2005 Response to Non-Final Office Action
09/892981	03-15-2005 Notice of Non-Responsive Amendment
09/892981	02-24-2005 Response to Non-Final Office Action
09/892981	08-25-2004 Non-Final Office Action
09/892981	04-16-2004 RCE and Response to Final Office Action
09/892981	02-09-2004 Advisory Action
09/892981	12-16-2003 Response to Final Office Action
09/892981	10-16-2003 Final Office Action

09/892981	07-25-2003 Response to Non-Final Office Action
09/892981	02-26-2003 Non-Final Office Action
09/892981	11-26-2002 RCE and Response to Final Office Action
09/892981	08-27-2002 Final Office Action
09/892981	06-07-2002 Response to Non-Final Office Action
09/892981	02-08-2002 Non-Final Office Action
10/099725	01-29-2003 Office Action
10/099725	10-01-2002 Office Action
10/456868	01-12-2006 Non-final Office Action
10/456868	04-25-2006 Response to Non-Final Office Action
10/456868	06-28-2006 Final Office Action
10/456868	11-28-2006 Declaration of Valerie Masini-Eteve
10/456868	11-28-2006 Response to Final Office Action
10/456868	04-25-2007 RCE and Response to Final Office Action
10/456868	04-25-2007 Declaration of Valerie Masini-Eteve
10/456868	08-05-2009 Non-Final Office Action
10/456868	02-04-2010 Declaration under 37 CFR 1.131
10/456868	02-04-2010 Response to Non-Final Office Action
10/456868	05-11-2010 Non-Final Office Action
10/456868	08-11-2010 Response to Non-final Office Action
10/456868	10-27-2010 Non-Final Office Action
10/099725	01-29-2003 Non-Final Office Action
10/436380	08-05-2009 Response to Amendment under Rule 312
10/436380	07-23-2009 Amendment After Notice of Allowance

10/436380	05-13-2009 Notice of Allowance
10/436380	04-22-2009 Response to Final Office Action
10/436380	01-23-2009 Final Office Action
10/436380	10-28-2008 Response to Non-Final Office Action
10/436380	10-28-2008 Declaration of Russel Potts
10/436380	10-28-2008 Declaration of Olivier Raux
10/436380	05-28-2008 Non-Final Office Action
10/436380	05-02-2008 RCE and Response to final Office Action
10/436380	01-02-2008 Final Office Action
10/436380	11-19-2007 Response to Non-Final Office Action
10/436380	07-17-2007 Non-Final Office Action
10/436380	01-03-2007 Non-Final Office Action
10/436380	07-03-2006 Non-Final Office Action
11/662339	10-04-2010 Response to Non-Final Office Action
11/662339	06-14-2010 Non-Final Office Action
11/662339	02-22-2010 Response to Non-Final Office Action
11/662339	09-22-2009 Non-Final Office Action
11/662339	05-29-2009 Response to Non-Final Office Action
11/662339	02-03-2009 Non-Final Office Action
10/099725	01-29-2003 Non-Final Office Action
10/099725	09-29-2003 Notice of Abandonment
09/651777	06-19-2001 Non-Final Rejection
09/651777	10-29-2001 Response after Non-Final Action
09/651777	10-29-2001 Declaration of Jean-Louis Anspach

09/651777	12-21-2001 Supplemental Amendment
09/651777	01-16-2002 Supplemental Amendment
09/651777	02-08-2002 Supplemental Amendment II
09/651777	02-06-2002 Declaration of Robert E. Dudley dated (submitted with the Supplemental Amendment II dated 02-08-2002)
09/651777	04-01-2002 Letter in response to 03-28-2002 Examiner Interview
09/651777	05-07-2002 Non-Final Rejection
09/651777	05-20-2002 Response after Non-Final Action
09/651777	07-23-2002 Supplemental Response After Interview
09/651777	07-23-2002 Declaration of Michele Alm
09/651777	07-23-2002 Declaration of Sandy Faulkner
09/651777	07-24-2002 Supplemental Response
09/651777	08-01-2002 Supplemental Response
09/651777	08-20-2002 Protest under 37 CFR §1.291(a)
09/651777	08-13-2002 Notice of Allowance
09/651777	06-12-2003 Request for Certificate of Correction under 37 CFR §1.322 (2 pages of corrections)
09/651777	06-12-2003 Request for Certificate of Correction under 37 CFR §1.323 (1 page of corrections)
09/651777	10-17-2003 Certificate of Correction
09/651777	11-29-2004 Petition to correct inventorship under 35 USC §256, 37 CFR §1.324, and M.P.E.P. §1481 (a certificate of correction is submitted)
09/651777	03-27-2007 Decision Granting Petition to Correct Inventorship under 37 CFR §1.324
09/651777	04-30-2007 Certificate of Correction
09/651777	05-22-2007 Certificate of Correction - Correction of Inventors

09/703753	04-24-2001 Non-Final Rejection
09/703753	08-24-2001 Response after Non-Final Action
09/703753	11-23-2001 Final Rejection
09/703753	02-22-2002 Notice of Appeal and Amendment/Argument after Notice of Appeal
09/703753	03-22-2002 Advisory Action
09/703753	06-05-2002 Non-Final Rejection
09/703753	10-21-2002 Response after Non-Final Action
09/703753	01-15-2003 Non-Final Rejection
09/703753	04-09-2003 Response after Non-Final Action
09/703753	06-19-2003 Response after Non-Final Action
09/703753	08-26-2003 Final Rejection
10/046454	09-10-2002 Non-Final Rejection
10/046454	09-20-2002 Response after Non-Final Action
10/046454	12-09-2002 Supplemental amendment
10/046454	01-27-2003 Notice of Allowance
10/046454	06-13-2003 Request for Continued Examination (RCE), Petition to Withdraw, and Supplemental amendment
10/046454	06-18-2003 Petition Decision of Granted to Withdraw from Issue
10/046454	07-11-2003 Supplemental Amendment B
10/046454	10-16-2003 Non-Final Rejection
10/828678	06-25-2008 Non-Final Rejection
10/098232	07-31-2003 Preliminary Amendment
10/098232	10-20-2003 Non-Final Rejection
10/098232	11-14-2007 Request under Rule 48 correcting inventorship

10/825540	06-20-2008 Non-Final Rejection
10/153468	02-24-2004 Non-Final Rejection
10/153468	08-24-2004 Response after Non-Final Action
10/153468	11-17-2004 Final Rejection
10/867435	06-09-2008 Non-Final Rejection
10/867435	12-09-2008 Response after Non-Final Action
10/867435	03-11-2009 Final Rejection
10/867435	09-11-2009 Request for Continued Examination and Amendment
10/867435	12-04-2009 Non-Final Rejection
10/867435	06-04-2010 Response after Non-Final Action
10/867435	08-13-2010 Final Rejection
10/867445	03-11-2008 Non-Final Rejection
10/867445	06-24-2008 Response after Non-Final Action
10/867445	10-10-2008 Non-Final Rejection
10/867445	04-10-2009 Response after Non-Final Action
10/867445	07-15-2009 Final Rejection
10/867445	12-14-2009 Request for Continued Examination and Amendment
10/867445	01-19-2010 Non-Final Rejection
10/867445	07-19-2010 Response after Non-Final Action
10/867445	09-24-2010 Final Rejection
10/787071	10-02-2007 Non-Final Rejection
10/787071	02-01-2008 Response after Non-Final Action
10/787071	05-29-2008 Final Rejection
10/531526	03-18-2008 Non-Final Rejection

10/531526	07-17-2008 Response after Non-Final Action
10/531526	11-17-2008 Final Rejection
10/531526	05-12-2009 Request for Continued Examination (RCE) and Amendment
10/531526	07-09-2009 Non-Final Rejection
10/531526	12-08-2009 Response after Non-Final Action
10/531526	02-22-2010 Final Rejection
10/531526	08-20-2010 Request for Continued Examination (RCE) and Amendment
10/033101	01-10-2003 Non-Final Rejection
10/033101	05-12-2003 Response after Non-Final Action
10/033101	06-03-2003 Supplemental Amendment and Request for Interview
10/033101	06-30-2003 Supplemental Amendment B
10/033101	10-21-2003 Final Rejection
12/543541	08-19-2009 Petition for 12-month Accelerated Exam, Pre-examination search document; accelerated examination support document
12/543541	12-07-2009 Petition for 12-month Accelerated Exam Decision – Granted
12/543541	01-28-2010 Examiner Interview Summary Record
12/543541	02-02-2010 Applicants' comments to Examiner-initiated interview summary
12/543541	02-05-2010 Non-Final Rejection
12/543541	03-05-2010 Response after Non-Final Action
12/543541	04-05-2010 Final Rejection
12/543541	10-05-2010 Request for Continued Examination (RCE) and Amendment

12/543541	11-09-2010 Non-Final Rejection
10/829618	05-14-2008 Non-Final Rejection
10/829618	11-13-2008 Response after Non-Final Action
10/829618	02-05-2009 Non-Final Rejection
10/829618	08-05-2009 Response after Non-Final Action
10/829618	11-30-2009 Non-Final Rejection
10/829618	06-01-2010 Response after Non-Final Action
10/829618	08-11-2010 Notice of Allowance
10/925421	11-24-2008 Non-Final Rejection
10/925421	05-26-2009 Response after Non-Final Action
10/925421	09-29-2009 Final Rejection
10/925421	03-29-2010 Response after Final Action and RCE
10/925421	10-12-2010 Non-Final Rejection
10/248267	12-15-2003 Non-Final Rejection
10/273484	12-15-2003 Non-Final Rejection

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute “prior art.” If the Examiner applies the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute “prior art” under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

Applicants believe no additional fee is due in connection with this submission.
However, if any additional fee is due, or if any overpayment has been made, the Commissioner is
authorized to charge any such fee or credit any overpayment to our Deposit Account No. 02-4377.

Respectfully submitted,

Date: November 12, 2010



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